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STRAWB2 (Stress and Wellbeing After Childbirth): a randomised controlled trial of targeted self-help materials to prevent post-traumatic stress disorder following childbirth

Slade , Pauline ; West , Helen; Thompson , Gill ; Lane, Steven; Spiby , Helen ; Edwards, Rhiannon Tudor; Charles, Joanna; Garrett , Charlotte ; Flanagan , Beverley ; Treadwell , Maureen ; Hayden , Emma ; Weeks , Andrew

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STRAWB2 (Stress and Wellbeing After Childbirth): a randomised controlled trial of targeted self-help materials to prevent post-traumatic stress disorder (PTSD) following childbirth

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67 Liverpool Womens Hospital Foundation Trust and Liverpool Health Partners

68 Liverpool

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72 **Shortened running title: Preventing Post Traumatic Stress after Childbirth**

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79

80 **Abstract:**

81 **Background**

82 Post-traumatic stress disorder (PTSD) can develop after a traumatic childbirth.

83

84 **Objective**

85 To test if providing psychological self-help materials would significantly lower the incidence of

86 PTSD at 6-12 weeks postnatally.

87

88 **Design**

89 Open label, randomised controlled trial, blinded outcome assessment.

90

91 **Setting**

92 Community midwifery services in two North West NHS Trusts

93

94 **Sample**

95 2419 women receiving usual NHS postnatal care

96

97 **Methods**

98 Midwives screened women for traumatic birth experience. 678 women who screened positive

99 (28.1%) were randomly allocated to self-help with usual care (n=336) or usual care alone (n=342).

100 Self-help materials, were a leaflet and on-line film designed to prevent the development of PTSD

101 after trauma exposure through how to manage early psychological responses.

102

Main Outcome Measure

The primary outcome was a composite of diagnostic and sub-diagnostic PTSD at 6-12 weeks postnatally using the gold standard Clinician Administered PTSD Interview (CAPS-5).

Results

478 of 678 (70.5%) correctly randomised women and 9 randomised in error were followed up. Diagnostic or sub-diagnostic PTSD rates at follow-up did not differ between groups who received self-help (26.7%, 65/243) or usual care alone (26.2%, 64/244) (ITT analysis: relative risk (RR) 1.02, 95% confidence interval (CI) 0.68 to 1.53). Findings remained consistent in the per protocol analysis (RR 1.04, 95% CI 0.85 to 1.27). Women viewed the materials very positively. There were no adverse effects. Health economic micro-costing indicated implementation would be very low cost.

Conclusions

Many women experience a traumatic birth and risk developing PTSD, but self-help strategies without professional support are insufficient and should not be routinely introduced.

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Key Words : post traumatic stress disorder, postnatal, childbirth, prevention, randomised controlled trial

Trial registration ISRCTN 44832384

127 **Tweetable abstract.** Self-help information alone does not reduce the number of women developing
128 PTSD after a traumatic childbirth.
129
130

131 **Introduction**

132 Post-traumatic stress disorder (PTSD) after childbirth is a major cause of psychological distress, with
133 3% of women suffering at full diagnostic levels and 5-9% when sub-diagnostic levels (partial PTSD)
134 are included¹. When childbirth is experienced as traumatic, defined as high fear of death or damage
135 to self or baby during or shortly after childbirth, then women are at risk of developing PTSD²⁻⁵.
136 Other potential risk factors for PTSD include poor quality of interactions with staff, medical
137 interventions and previous psychiatric history or trauma ⁶. PTSD is debilitating and in the absence of
138 intervention tends to become chronic. As well as the distress for the woman PTSD can adversely
139 impact the child's cognitive, emotional and social development^{7,8} Prevention where possible is
140 therefore crucial.

141

142 Experiencing an event as traumatic does not inevitably lead to PTSD. Intrusive experiences
143 involving imagery and thoughts are normal responses to trauma that facilitate memory processing.
144 Where women view these as signs of illness or not coping and avoid these responses this contributes
145 to traumatic memories remaining unprocessed leading to PTSD⁹.

146

147 The STRAWB2 self-help materials (a leaflet and film) were designed to prevent the development of
148 PTSD. Experts by experience guided development to ensure accessibility, and materials were piloted
149 in a feasibility study¹⁰. The materials derive from evidence-based psychological theory ¹¹. They
150 incorporate explanations

151 1) Why women experience distressing responses to help normalize these responses and reduce their
152 negative evaluation.

153 2) Why it is important not to block unpleasant images and thoughts.

154 3) How supportive discussions help memory processing and provides an exercise to identify a
155 suitable person, time and place with whom to do this.

156 4) Exercises using implementation intentions throughout to help women translate their new
157 understandings into actions.

158 PTSD, treatment is expensive, so a simple and low-cost prevention package is attractive. However,
159 the evidence on whether psychoeducation and self-help can prevent PTSD is limited and
160 inconsistent^{12,13}. NICE antenatal and postnatal mental health guidelines ¹⁴ recommend researchers
161 develop effective psychological interventions for perinatal women, including gathering evidence of
162 cost-effectiveness..

163

164 This study aimed to evaluate whether providing self-help materials to women who have experienced
165 a traumatic childbirth reduced the incidence of PTSD 6-12 weeks postnatally at diagnostic and
166 subdiagnostic levels when compared with usual care and to provide a health economic analysis.

167 PTSD symptoms postnatally are particularly important because of transitions in and the formation of
168 new relationships. As a result of this critical salience NICE recommends that intervention is not
169 restricted to those with diagnostic level symptoms and indeed childbirth trauma services intervene at
170 non diagnostic levels. Therefore the protocol prespecified this combined outcome as the most
171 clinically appropriate. The specific criteria were chosen on the basis of the existing literature. This
172 helpfully meshed with the targeted dimensions of the prevention information.

173

174 **Methods**

175 **Study design**

176 STRAWB2 (Stress and Wellbeing After Childbirth) was a phase III multi-site randomised controlled
177 trial(RCT), evaluating whether providing a targeted sample of women with self-help materials
178 reduced the incidence of PTSD after childbirth when compared with usual care. We included clinical
179 and economic evaluation of cost per case prevented, and qualitative feedback from women on the
180 self-help materials. 125 community midwives were trained to recruit and randomise women, in
181 accordance with Good Clinical Practice standards.

182

183 **Participants**

184 Women aged 16 years or over, who had given birth to a live baby, and had sufficient English
185 language to complete the measures were eligible. An exclusion criterion was those receiving other
186 specialist services (enhanced midwifery for drug/alcohol or social care reasons, or perinatal mental
187 health teams). Study sites were Liverpool Women's NHS Foundation Trust and Lancashire Teaching
188 Hospitals NHS Foundation Trust with recruitment from May 2017 to September 2018.

189

190 **Randomisation and masking**

191 Eligible women were informed about the study at their first postnatal visit (home or community). At
192 a subsequent routine contact, following completion of routine postnatal care, and any actions or
193 advice based on clinical judgement, midwives asked women about participation. After providing
194 written informed consent, women were asked the screening questions to identify those who had
195 experienced birth as traumatic. This screening tool was based on DSM-IVR criteria and developed in
196 liaison with the Birth Trauma Association and piloted in the STRAWB feasibility study¹⁰.

197 *Thinking about your childbirth (and any time in hospital after) was there any time during this when*
198 *you felt (i) horror or helplessness about what was happening? (yes/no) (ii) really frightened about*
199 *your own or your baby's wellbeing? (yes/no).*

200

201 This tool incorporates both the perceived threat and the response, as women's appraisal during the
202 birth process is a key risk factor for PTSD onset ^{2,15}. Women answering 'yes' to either question were
203 randomised to self-help or usual care by their midwife, using an independent web-based system
204 (sealedenvelope.com). Owing to the nature of the materials being tested it was impossible to mask
205 women or midwives from treatment allocation.

206

207 **Procedures**

208 Women allocated to self-help received the leaflet and web-link from the midwife, and a reminder
209 text message two weeks later from a researcher not involved in analysis. All trial participants
210 received routine care from health visitor and GP over the follow up period. Information on
211 demographics, childbirth, and maternal and infant morbidity from women and their hospital records
212 was collected

213

214 Women were followed-up by telephone at 6-12 weeks postnatally, at least 4 weeks after
215 randomisation. They completed the CAPS clinical interview with researchers blinded to group
216 allocation and trained to prespecified criterion for reliable rating. Where diagnostic or sub-diagnostic
217 PTSD was identified, the woman's health visitor was informed.

218

219 **Outcomes**

220 The primary outcome was a composite of diagnostic and sub-diagnostic PTSD, assessed at 6-12
221 weeks postnatally using the gold standard CAPS-5 clinical interview. This derives directly from the

222 DSM-5 definition of diagnostic PTSD.. Sub-diagnostic PTSD was defined as meeting the diagnostic
223 threshold for criteria A (exposure) and G (distress or impairment in relation to the event), and
224 meeting the diagnostic threshold for at least one symptom from either criteria B (reexperiencing) or
225 C (avoidance). Secondary outcomes were depression and anxiety Hospital Anxiety and Depression
226 Scale (HADS)¹⁶, attachment Multidimensional Parental Attachment Scale (MPAS)¹⁷, couple
227 relationship quality (Dyadic Adjustment Scale (DAS4))¹⁸. Health service use was measured using a
228 bespoke Client Service Receipt Inventory (CSRI) questionnaire reporting all contacts with NHS
229 healthcare professionals from randomisation to follow-up, including consultations relating to birth
230 experience, whether routine or specially organised.

231

232 **Health economic micro-costing and service use analysis**

233 Micro-costing was used to detail costs of intervention delivery¹⁹. The intervention developers (PS,
234 HW) provided information regarding the cost of the self-help materials (leaflet and film), training
235 and number of midwives trained in the trial to deliver the intervention. Midwives were surveyed to
236 identify time taken for screening and information provision to screen positive women.

237

238 The micro-costing and a cost-consequence analysis were conducted from a service provider (NHS)
239 perspective using national unit costs for 2016-17) ^{20,21}.

240

241 **Feedback interviews**

242 To assess use of the leaflet and film, a convenience subsample of women in the self-help arm
243 completed a telephone interview covering:

- 244 (i) Whether they had used the materials;
- 245 (ii) What had been helpful or unhelpful;
- 246 (iii) Any actions taken as a result of the prevention information.

247 Descriptive (frequencies) and thematic analysis²² of the responses was undertaken.

248

249 **Sample size and statistical analysis**

250 Considering only screen positive women, to detect a reduction of PTSD cases from 25% to 15% at 6-
251 12 weeks follow up required a sample size of 247 women in each group (80% power at 5%
252 significance level). We analysed the primary outcome for both intention-to-treat (ITT) and per
253 protocol levels. For the latter, women who had screened negative to traumatic birth but were
254 randomised in error were excluded. The baseline demographic and clinical data were summarised
255 using standard summary statistics. For all primary and secondary outcomes relative risks or mean
256 differences, with 95% confidence intervals are reported.

257

258 Standard hypothesis tests, chi-squared, independent sample t-test etc. were used to determine if there
259 were any between-group differences in the primary and secondary outcome measures. Logistic
260 regression analysis was also used to calculate adjusted odds ratios for the primary outcomes when
261 controlling for the influence of known confounding variables. All hypothesis testing was undertaken
262 at the 5% significance level.

263

264 **Patient and Public Involvement**

265 Patients and public representatives were integral members of the trial management group and their
266 invaluable insights influenced the study from its inception, through implementation interpretation,
267 and dissemination. Our strategy incorporated national and local perspectives via the Birth Trauma
268 Association charity and a local expert by experience.

269

270 **Results**

271 Community midwives invited 3444 eligible women to participate. Of these, 2414 women consented
272 and were asked the two screening questions. 678 women screened positive (28.1%) and were
273 randomly allocated to either self-help with usual care (n=336) or usual care alone (n=342). These
274 women were included in the intention to treat and per protocol analyses. An additional 40 women
275 who had screened negative were randomised in error to self-help with usual care (n=25) or usual care
276 alone (n=15), were included in the intention to treat analysis. Any additional randomisation
277 violations and how managed are shown in Fig1.

278

279 **Site comparisons**

280 355 women were randomised at Liverpool Women's NHS Foundation Trust, and 363 at Lancashire
281 Teaching Hospitals NHS Foundation Trust (Preston and Chorley). The sites differed only in the
282 number of days postnatal when randomisation took place (median of 24 Liverpool and 12
283 Lancashire) reflecting differences in midwifery services. A greater proportion of women in
284 Liverpool lived in areas of higher deprivation. The demographic, obstetric and infant data of the 678
285 randomised women were similar in the two trial sites (Table S1).

286

287 **The sample in context**

288 Compared with all women who gave birth at these two locations during the study period, women
289 who screened positive were more likely to have: induction of labour, birth in theatre, instrumental
290 birth, emergency Caesarean section, blood loss over 1000ml, and infant Apgar<7 at 5 minutes. A
291 higher proportion of White British women took part, likely due partly to the inclusion criterion of
292 sufficient English language (Table S2).

293

294 **Baseline comparisons for self-help and usual care groups**

295 Baseline characteristics were comparable between the groups, except for induction of labour: self-
296 help 53.2% (183/344) and usual care 43.3% (146/337). There was a trend towards more women in
297 the self-help group having had skin-to-skin contact with their baby following birth: self-help 77.3%
298 (265/313), usual care 72.2% (242/306) and having experienced blood loss over 1000ml: self-help
299 19.7% (68/344), usual care 15.1% (51/337). More women who had assisted conception were
300 randomised to usual care (4.1%, 14/338) than self-help (0.9%, 3/342), although numbers are small
301 (Table 1).

302

303 **Follow-up**

304 We successfully followed-up 478 women who had been correctly randomised to self-help or usual
305 care (70.7%) at 6-12 weeks postnatally and at least 4 weeks after randomisation, and an additional 9
306 women who had been randomised in error (Figure 1).

307

308 **Primary outcome**

309 Using an intention to treat (ITT) analysis the proportion of women with diagnostic or sub-diagnostic
310 PTSD at follow-up did not differ between groups who received self-help materials (26.7%, 65/243)
311 or usual care alone (26.2%, 64/244) (relative risk (RR) 1.02, 95% confidence interval (CI) 0.68 to
312 1.53, P=0.92) (Table 2). Findings remained consistent in the per protocol analysis, excluding a small
313 number of screen negative women randomised by midwives in error (RR 1.04, 95% CI 0.85 to 1.27
314 (table S3), and when the ITT analysis was adjusted for induction and blood loss over 1000ml:
315 (adjusted odds ratio (AOR) 0.99, 95% CI 0.65 to 1.49) (Table 3).

316

317 **Secondary outcomes**

318 There were no differences identified in the ITT analysis of secondary outcomes of usual care alone
319 versus with self-help at follow-up, including whether women met the symptom threshold for

320 **criterion A: exposure to a traumatic experience** (RR 0.99, 95% CI 0.70 to 1.39), **criterion B:**
321 **intrusion symptoms** (RR 0.94, 95% CI 0.78 to 1.12), **criterion C: avoidance symptoms** (RR 0.85,
322 95% CI 0.70 to 1.04), **criterion D: cognitions and mood symptoms** (RR 0.98, 95% CI 0.80 to
323 1.19), **criterion E: arousal and reactivity symptoms** (RR 0.93, 95% CI 0.73 to 1.17), **criterion G:**
324 **distress or impairment** (RR 1.01, 95% CI 0.83 to 1.22) (Table 2).

325

326 The self-help materials were particularly targeted at symptoms in criteria B and C, and it is worth
327 noting that fewer women in the self-help group experienced these symptoms (**criterion B:** self-help:
328 87 (37.7%), usual care: 97 (40.8%); **criterion C:** self-help: 46 (19.5%), usual care: 61 (25.3%)).
329 However, these differences did not reach statistical significance.

330 There were also no differences between women in the self-help versus usual care groups for: **anxiety**
331 (mean difference (MD) -0.29, 95% CI -1.03 to 0.45), **depression** (MD 0.31, 95% CI -0.30 to 0.91) as
332 measured by the Hospital Anxiety and Depression Scale (HADS) at follow-up; The
333 Multidimensional Parental Attachment Scale(MPAS) questionnaire **Quality of attachment** to the
334 infant (MD -0.43, 95% CI -1.30 to 0.50), **Absence of hostility** towards the infant (MD -0.29, 95% CI
335 -0.93 to 0.35), and **Pleasure in interaction** with the infant (MD 0.07, 95% CI -0.57 to 0.72), or the
336 DAS4 questionnaire covering the **quality of the couple's relationship** (MD -0.04, 95% CI -0.69 to
337 0.61) (Table 2).

338

339 **Comparison of screen positive and screen negative women.**

340 Comparison of the women who screened positive for a traumatic birth (n=688) and those who
341 screened negative (n=1726) showed that those who screened positive were more likely to be
342 nulliparous, but for other demographics the groups were comparable (Table S4).

343

344 **Comparison of those completing both time points and those lost to the study**

345 Follow-up was completed for 478 of the 678 women randomised (70.5%). Comparison of the
346 demographic, obstetric and infant variables between those completed and who did not complete
347 follow-up showed no differences between the groups (Table S5). Of the women followed up, 236
348 had been randomised to self-help, and 242 to usual care. There were no differences between self-help
349 and usual care in women followed-up, apart from those already observed between the groups of
350 women randomised (fewer women in the self-help group had assisted conception, more women in
351 the self-help group had induction of labour, skin-to-skin contact, and blood loss over 1000ml (Table
352 S5)).

353

354 **Film analytics**

355 Film analytics indicated that the film which was hidden from search engines was watched 67 times
356 (to 26th Sept 2018). It was impossible to know if these were different or the same individuals.

357

358 **CAPS fidelity monitoring**

359 To ensure consistency between the four researchers conducting CAPS interviews, the transcripts of
360 143 interviews were coded by two researchers independently: all diagnostic, sub-diagnostic and 20%
361 of non-diagnostic interviews, until July 2018. The overall agreement on diagnostic category between
362 coders across all interviews was 90.4%. Cohen's Kappa across all raters for all interviews was 0.80,
363 classified as excellent²³.

364

365 **Feedback interviews**

366 A convenience sample of 83 (34.4% of the 241 women randomised to self-help who completed
367 follow-up) took part in a feedback interview. Comparisons of demographic, obstetric and follow-up
368 data showed no systematic differences between these women and others randomised to self-help.

369 Most women remembered receiving the leaflet (N= 77/83; **92.8%**) and had read the leaflet

370 (N=68/75; **90.7%**). Of those who had read it, most women read it once (N=47/70; **67.1%**). The
371 majority of women “Agree” (N= 43/69; **62.3%**) or “Strongly Agree” (N= 14/69; **20.3%**) that they
372 found the leaflet useful. The majority of women “Agree” (N= 40/69; **58.0%**) or “Strongly Agree”
373 (28/69; **40.6%**) that they found the leaflet easy to understand. Most women did not remember
374 receiving the web-link (N= 44/78; **56.4%**) and had not watched the film (N= 48/52; **92.3%**). From
375 this sample, only 4 women said they had watched it. Most women preferred a leaflet format (N=
376 54/68; **79.4%**).

377

378 The key qualitative findings were:

- 379 • Many women liked the design of the materials and information included.
- 380 • It helped women understand and to normalise some of the feelings they experienced after
381 birth.
- 382 • It helped open channels of communication (including professional and personal support).
- 383 • Some suggested that they would like a clearer link to web materials (despite the link being
384 cited twice in the leaflet and embedded in the reminder text message).
- 385 • Some suggested the intervention may have been more beneficial if supported by healthcare
386 professionals.

387

388 **Health economic micro-costing and service use analysis**

389 Intervention costs within the research context ranged from £4 to £6 per woman, based on 2,409
390 women screened. .

391

392 For implementation in a maternity service of 60 midwives, costs would be £3,402 (£57 per midwife)
393 for the set-up year, reducing to £1,731 (£29 per midwife) for subsequent years training for
394 returners/new starters and updating. . Using current predominant models of working (non-continuity)

395 estimates of a case load of 100 women per annum per midwife prorated to 70 to account for part-
396 time working equates to costs of £0.81 per woman in year of service set up for training of midwives
397 and £0.41 in maintenance years. There is also the cost of the self-help materials (£0.56 per screen
398 positive woman prorated to £0.16 across the postnatal population) and time for the midwives to
399 screen (2.8 minutes) and provide materials (3 minutes) for those screen positive.. and -

400

401 Non-routine service use for both groups was minimal.

402 **Discussion**

403 **Main findings**

404 We evaluated the effect of providing information about the normality of early trauma responses and
405 how best to manage these for women who had a traumatic birth. This was ineffective in reducing the
406 incidence of PTSD at diagnostic (full) and sub-diagnostic (partial) levels at 6-12 weeks postnatally.
407 Given that there was no difference in the incidence of PTSD, the lack of difference in secondary
408 outcomes was unsurprising. A reduction of PTSD symptoms would have formed the mechanism
409 behind other predicted differences.

410

411 Women valued the information, there were no adverse effects, and it did not increase distress.

412 Midwives found it easy to implement the screening tool and administer materials, and it is very low-
413 cost. In its current form, it was insufficient to prevent the development of PTSD following childbirth.

414 Qualitative results indicate that it might be more effective if supported with active input from
415 midwives or health visitors which could facilitate use by giving permission for self-care and through
416 providing practice of the strategies.

417

418 **Strengths and limitations**

419 This is the first trial of a self-help intervention derived directly from psychological theory to prevent
420 PTSD following traumatic childbirth. Bias was minimised by using an independent web-based
421 service to generate the randomisation list and conceal allocation. Researchers who assessed
422 outcomes were blinded to allocation, and the inter-rater reliability was high. Samples were well
423 matched and sufficient for power. Follow up rates are acceptable at a typical level for psychological
424 intervention studies, and there is no evidence that samples differed on this basis. Clearly those lost to
425 follow up could impact on findings All outcomes are reported according to the prespecified data
426 management plan, and there is minimal missing data. We believe this trial provides robust evidence.

427

428 It is unusual to have 125 community midwives across two sites recruiting to a trial. Overall this
429 worked successfully and enabled ambitious randomisation targets to be reached. The trial design also
430 benefitted from being fitted into usual care to reflect a real world evaluation. The challenges included
431 maintaining consistency and a higher number of women than expected were randomised in error.
432 However, the per protocol analysis shows consistent findings.

433

434 Limitations are that the study tested provision rather than use of the self-help materials. The feedback
435 interviews were from a convenience rather than random sample. They indicate that most women read
436 the leaflet but did not access the film. In the first few months with a newborn baby a woman's
437 attention is naturally focused on her infant, and it may be difficult to legitimize or find time to attend
438 to her own self-care. Therefore, women may have found it difficult to prioritise the exercises in the
439 leaflet. Feedback interviews suggested that it may be more effective if midwives or health visitors
440 supported and prompted use of the self-help materials. Due to the study design, we had specifically
441 emphasised in training that midwives should not change their practice, to ensure that women
442 received their usual care before trial procedures were initiated and to avoid exposing women in the
443 usual care group to principles from the self-help materials.

444

445 It is possible that the screening triggered women in the control group to access other web based
446 material but the frequency of this was equivalent in both groups (N=17). In addition the sites women
447 reported using do not have equivalent material to this novel intervention. The model of screening and
448 provision of information tests the broad utility of this package and readiness to utilize and therefore
449 potential effectiveness may be higher in women who actively seeking information. Finally outcomes
450 were only assessed between 6- 12 weeks and PTSD with deferred onset can occur. Longer term
451 follow up might yield different results.

452

453 **Interpretation**

454 Leaflets are often introduced into practice without evidence of impact. During the trial we repeatedly
455 encountered attitudes that testing the materials was unnecessary, as a prevention package based on
456 sound psychological principles must be a “good thing”. Wessley et al ¹² found that despite the
457 ubiquity of psychoeducation following trauma, evidence supporting its use was rare. Only one direct
458 trial of psychoeducation was identified²⁴; an RCT of self-help material for civilian trauma victims
459 presenting at an Accident and Emergency department. There was no evidence of positive impact but
460 the material provided was long, dense and inaccessible.

461

462 Indirect evidence concerning the effectiveness of psychoeducation is mixed ¹². Participants receiving
463 psychoeducation in RCTs have had modest improvements, although the interventions were to treat
464 rather than prevent PTSD, and effects may be due to trial participation rather than the intervention
465 itself²⁵⁻²⁹. A meta-analysis of four studies³⁰ concluded that passive psychoeducational interventions
466 could effectively reduce symptoms of depression and psychological distress. However, this overall
467 effect masks the finding that there was no improvement in the one included study of psychological
468 distress alone³¹. STRAWB2 materials moved beyond passive psychoeducation: tasks encouraged

469 women to practice adaptive responses to facilitate memory processing, so the studies are not directly
470 comparable. None of these trials focused in the early postnatal period when it may be difficult
471 legitimizing time for self-care and self-help.

472

473 A recent systematic review of interventions to prevent PTSD following childbirth(34), concluded
474 that there was insufficient evidence that interventions tested to date prevent PTSD following
475 traumatic childbirth. This study further extends that finding.

476

477 **Conclusions**

478 Over a quarter of women in this UK sample experienced birth as traumatic, and 26% of these women
479 developed diagnostic or subdiagnostic PTSD by 6-12 weeks postnatally. This indicates an overall
480 sample rate of 7.5% which concurs with existing information [1] and further underlines PTSD after
481 childbirth as a significant problem. A robust test of providing of self-help materials well grounded in
482 psychological theory, showed these did not prevent the development of PTSD. Although providing
483 information may be considered important, it was inadequate to generate clinical change. Our study
484 should urge caution in the distribution of psychoeducational self-help following trauma, as such
485 minimalist approaches appear to be an ineffective use of resources and may provide inappropriate
486 reassurance that a vulnerable group are receiving an appropriate help. When trying to extract
487 maximum value from limited budgets and where the need to be seen to be ‘doing something’ is
488 powerful, such minimalist approaches whilst superficially attractive, may be false economy in
489 relation to trauma.

490

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497 **Ethical approval**

498 This was given by the North West - Liverpool Central Research Ethics Committee (16/NW/0680)
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501

502 **Transparency statement**

503 Professor Slade as lead author affirms this manuscript is an honest, accurate and transparent account
504 of the study and no important aspects are omitted. All authors had access to the data and the study
505 was entirely independent from funders.

506

507 **Author Contributions**

508 PS was principal investigator and took overall responsibility for the trial. She was instrumental in its
509 conception, planning, carrying out, analysing and writing up. HW was the principal researcher for
510 the trial managing all other researchers and completing data collection and providing first draft of the
511 paper. GT was a site lead and contributed to ensuring quality standards of the work carried out and
512 the interpretation and paper. SL the trial statistician was involved in the conception, design and
513 completed the analysis and contributed to the paper. HS was instrumental in conception, design,
514 provided midwifery oversight and input to the write up. RTE oversaw the health economic aspect
515 was involved in conception, design, analysis and write up. JMC contributed to the health economic
516 design and analysis and contributed to the paper. CG was involved in midwifery training, data
517 collection and oversaw fidelity checking for CAPS5 and contributed to the paper. BF provided
518 midwifery training and support, data collection and contributed to the paper. MT and EH provided

our public and patient involvement. MT on behalf of the Birth Trauma Association advised on all aspects from conception to completion including the paper. EH was involved in advising on the running of the trial, its interpretation, played major role in dissemination activities and contributed to the paper. AW was instrumental in conception, design, provided obstetric oversight and input to the write up.

524

525 **Conflict of Interest Declaration**

No author has conflicts of interest in relation to the paper. HW's post at University of Liverpool was funded by the NIHR grant to work as a postdoctoral research associate on the trial. All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/coi_disclosure.pdf and declare: no support from or any financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

532

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Table 1: Demographic and Obstetric: Self-help (intervention) versus Usual care (control) (randomised women).

Variable		Self-help ¹² N=346	Usual care ¹² N=345
Age	mean(st. dev)	30.10 (5.09)	30.39 (5.26)
Parity	median(IQR)	1 (1)	1 (1)
	range	1 - 5	1 – 7
Ethnicity n(%)	<i>White</i>	290 (88.4)	300 (90.6)
	<i>Asian/Asian British</i>	15 (4.6)	17 (5.1)
	<i>Black/African/Caribbean</i>	3 (0.9)	3 (0.9)
	<i>Other</i>	20 (6.0)	11 (3.3)
Days postnatal at recruitment	median(IQR)	16 (14)	16 (13)
	Range	2 - 70	5 - 84
Highest qualification n(%)	<i>Degree/Higher degree</i>	158 (48.2)	153 (45.8)
Relationship status n(%)	<i>Living together</i>	123 (37.5)	140 (42.2)
	<i>Married</i>	168 (51.2)	160 (48.2)
	<i>Single/divorced/widowed/not answered</i>	37 (9.8)	32 (9.6)
Conception n(%)	<i>Natural</i>	339 (99.1)	324 (95.9)
	<i>Assisted</i>	3 (0.9)	14 (4.1)
Analgesia n(%)	<i>Regional anaesthetic</i>	166 (48.0)	173 (51.2)
	<i>General anaesthetic</i>	20 (5.8)	24 (7.2)
	<i>Inhaled nitrous oxide / oxygen</i>	59 (17.1)	62 (18.6)
	<i>Opiates</i>	69 (19.9)	52 (15.6)
	<i>None /non pharm /not recorded</i>	32 (9.2)	22 (6.6)
Place of birth n(%)	<i>Theatre</i>	132 (38.2)	128 (37.9)
	<i>Midwife led unit</i>	55 (15.9)	47 (13.9)
	<i>Consultant led unit</i>	154 (44.5)	155 (45.9)
	<i>Homebirth</i>	2 (0.6)	5 (1.5)
	<i>Unplanned outside maternity unit</i>	2 (0.6)	3 (0.9)
	<i>Maternity assessment unit</i>	1 (0.3)	0 (0)
Mode of birth n(%)	<i>Spontaneous</i>	145 (42.3)	146 (43.3)
	<i>Instrumental</i>	85 (24.8)	71 (21.1)
	<i>Emergency CS</i>	91 (26.5)	84 (24.9)
	<i>Elective CS</i>	22 (6.4)	36 (10.7)
Labour induced n(%)		183 (53.2)	146 (43.3)
Episiotomy n(%)		82 (23.1)	74 (21.9)
Perineal trauma n(%)	<i>No</i>	239 (70.9)	230 (70.3)
	<i>1st degree perineal tear</i>	16 (4.7)	14 (4.3)
	<i>2nd degree perineal tear</i>	94 (19.0)	67 (20.5)
	<i>3rd degree perineal tear</i>	18 (5.3)	13 (4.3)
Blood loss >1000ml n(%)		68 (19.7)	51 (15.1)
Apgar <7 at 5 minutes n(%)		16 (4.6)	19 (5.7)
NICU admission n(%)		24 (6.9)	26 (7.6)

¹Includes women randomised in error.

²Numbers may not add up to total due to missing data.

626 **Table 2: Trial outcomes: Self-help (intervention) versus Usual care (control) Intention to treat analysis (followed-up women).**

Variable		Self-help ¹² N=243	Usual care ¹² N=244	Difference (95% CI) Relative risk (95%CI)	Significance
PTSD Diagnosis	<i>None</i>	178 (73.3)	179 (73.7)		
	<i>Partial</i>	49 (20.2)	43 (17.7)		
	<i>Full</i>	16 (6.6)	21 (8.6)	1.02 (0.68, 1.53) ^{6,7}	P=0.92 ³
CAPS Criterion A met n(%) (Trauma exposure)	<i>No</i>	23 (9.5)	18 (7.4)		
	<i>Yes</i>	220 (90.5)	226 (92.6)	0.87 (0.61, 1.24) ⁶	P=0.41 ³
CAPS Criterion B met n(%) (Intrusion symptoms)	<i>No</i>	151 (63.4)	142 (59.2)		
	<i>Yes</i>	87 (36.6)	98 (40.18)	0.92 (0.76, 1.10) ⁶	P=0.34 ³
CAPS Criterion C met n(%) (Avoidance symptoms)	<i>No</i>	197 (81.1)	181 (74.5)		
	<i>Yes</i>	46 (18.9)	62 (25.5)	0.83 (0.67, 1.01) ⁶	P=0.08 ³
CAPS Criterion D met n(%) (Cognitions & mood symptoms)	<i>No</i>	181 (74.8)	178 (73.3)		
	<i>Yes</i>	61 (25.2)	65 (26.7)	0.96 (0.79, 1.17) ⁶	P=0.70 ³
CAPS Criterion E met n(%) (Arousal & reactivity symptoms)	<i>No</i>	208 (86.0)	203 (83.5)		
	<i>Yes</i>	34 (14.0)	40 (16.5)	0.91 (0.73, 1.15) ⁶	P=0.46 ³
CAPS Criterion G met n(%) (Distress & impairment symptoms)	<i>No</i>	169 (69.8)	168 (68.1)		
	<i>Yes</i>	73 (30.2)	75 (30.9)	0.98 (0.81, 1.19) ⁶	P=0.87 ³
HADS Anxiety mean(st. dev)		5.63 (4.16)	5.40 (3.95)	-0.23 (-0.97, 0.49) ⁵	P=0.53 ⁴
HADS Depression mean(st. dev)		3.77 (3.23)	4.13 (3.43)	0.35 (-0.28, 0.91) ⁵	P=0.25 ⁴
MPAS Quality of attachment mean(st. dev)		41.02 (4.92)	40.57 (4.97)	-0.43 (-1.31, 0.45) ⁵	P=0.34 ⁴
MPAS Absence of hostility mean(st. dev)		20.87 (3.68)	20.52 (3.32)	-0.33 (-0.98, 0.28) ⁵	P=0.28 ⁴
MPAS Pleasure in interaction mean(st. dev)		22.27 (3.35)	22.39 (3.81)	0.10 (-0.54, 0.74) ⁵	P=0.76 ⁴
DAS4 total mean(st. dev)		17.13 (3.61)	17.00 (3.63)	-0.12 (-0.76, 0.52) ⁵	P=0.71 ⁴

627 ¹Includes women randomised in error.

628 ²Numbers may not add up to total due to missing data.

629 ³Chi-squared test

630 ⁴Independent sample t-test

631 ⁵Mean difference

632 ⁶Relative risk

633 ⁷Comparison full/partial against none

634

635 **Table 3: Trial outcomes: Self-help (intervention) versus Usual care (control) Intention to treat analysis adjusted for induction and Blood loss >1000ml**
636 **(followed-up women).**

Variable		Self-help ¹² N=243	Usual care ¹² N=244	Adjusted Odds ratio (95%CI)	Significance
PTSD Diagnosis	<i>None</i>	178 (73.3)	179 (73.7)		
	<i>Partial/Full</i>	65 (26.7)	63 (26.63)	0.99 (0.65, 1.49)	P=0.95 ³
CAPS Criterion A met n(%) (Trauma exposure)	<i>No</i>	23 (9.5)	18 (7.4)		
	<i>Yes</i>	220 (90.5)	226 (92.6)	0.70 (0.35, 1.35)	P=0.28 ³
CAPS Criterion B met n(%) (Intrusion symptoms)	<i>No</i>	151 (63.4)	142 (59.2)		
	<i>Yes</i>	87 (36.6)	98 (40.18)	0.82 (0.56, 1.19)	P=0.29 ³
CAPS Criterion C met n(%) (Avoidance symptoms)	<i>No</i>	197 (81.1)	181 (74.5)		
	<i>Yes</i>	46 (18.9)	62 (25.5)	0.64 (0.41, 0.99)	P=0.047 ³
CAPS Criterion D met n(%) (Cognitions & mood symptoms)	<i>No</i>	181 (74.8)	178 (73.3)		
	<i>Yes</i>	61 (25.2)	65 (26.7)	0.86 (0.57, 1.31)	P=0.71 ³
CAPS Criterion E met n(%) (Arousal & reactivity symptoms)	<i>No</i>	208 (86.0)	203 (83.5)		
	<i>Yes</i>	34 (14.0)	40 (16.5)	0.72 (0.43, 1.21)	P=0.21 ³
CAPS Criterion G met n(%) (Distress & impairment symptoms)	<i>No</i>	169 (69.8)	168 (68.1)		
	<i>Yes</i>	73 (30.2)	75 (30.9)	0.92 (0.62, 1.38) ⁶	P=0.69 ³
HADS Anxiety mean(st. dev)		5.63 (4.16)	5.40 (3.95)	-0.23 (-0.97, 0.49) ⁵	P=0.97 ⁴
HADS Depression mean(st. dev)		3.77 (3.23)	4.13 (3.43)	0.35 (-0.28, 0.91) ⁵	P=0.38 ⁴

637 ¹ Includes women randomised in error.

638 ² Numbers may not add up to total due to missing data.

639 ³ Logistic regression

640 ⁴ Analysis of covariance

641 ⁵ Mean difference

642 ⁶ Relative risk

643

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